WITS PAEDIATRIC HIV CLINICS

# South African national paediatric HIV guidelines: challenges in development and implementation

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# Background

- Prior to ARV rollout NDoH commissioned continuum of care (CoC) guidelines for HIV in mid 2003
- Comprehensive guidelines for HIV infected children needed to be developed
- Antiretroviral treatment guidelines were to be included

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# Background

- Existing Gauteng, Western Cape and WHO guidelines formed the basis
- Experts from centres around the country were consulted on draft guidelines → consensus
- Paediatric regimens were proposed
- Draught guidelines were circulated → confusion

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# Background

- National Treatment handbook printed in mid 2004 containing finalised paediatric regimens
  - Not widely disseminated
- The guideline document for comprehensive paediatric HIV management was submitted January 2005 finally printed in October 2005

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# Challenges

- SA is a diverse country
- Evidence gaps
- Ever-emerging new evidence requires regular updates
- Lack of experience of provision of ARV care in public service → difficulty anticipating complexity of devising guideline for program of this proportion
- Guidelines provide framework within which to standardise practices
  - Absence of guidelines seen as reason for not providing care
  - Conversely guidelines themselves can become barrier if optimal conditions not perceived to be in place

# South African Guidelines for the management of Paediatric HIV infection

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- Advocacy document
- Promote comprehensive care for HIV-infected children
- Aimed to be used by both Primary Health Care Workers and other levels of care

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# Early Infant Diagnosis

- Data from research by Prof Gayle Sherman → change in policy
  - Single DNA PCR from 6 weeks of age + clinical signs provides almost 100% sensitivity for diagnosis and is affordable
- Guidelines recommend all HIV-exposed infants have DNA PCR as early as 6 weeks
- Now being scaled up but has been slow
  - Mainly due to lack of confidence by health care providers to take blood from children
  - Dry Blood Spots now being implemented in the field

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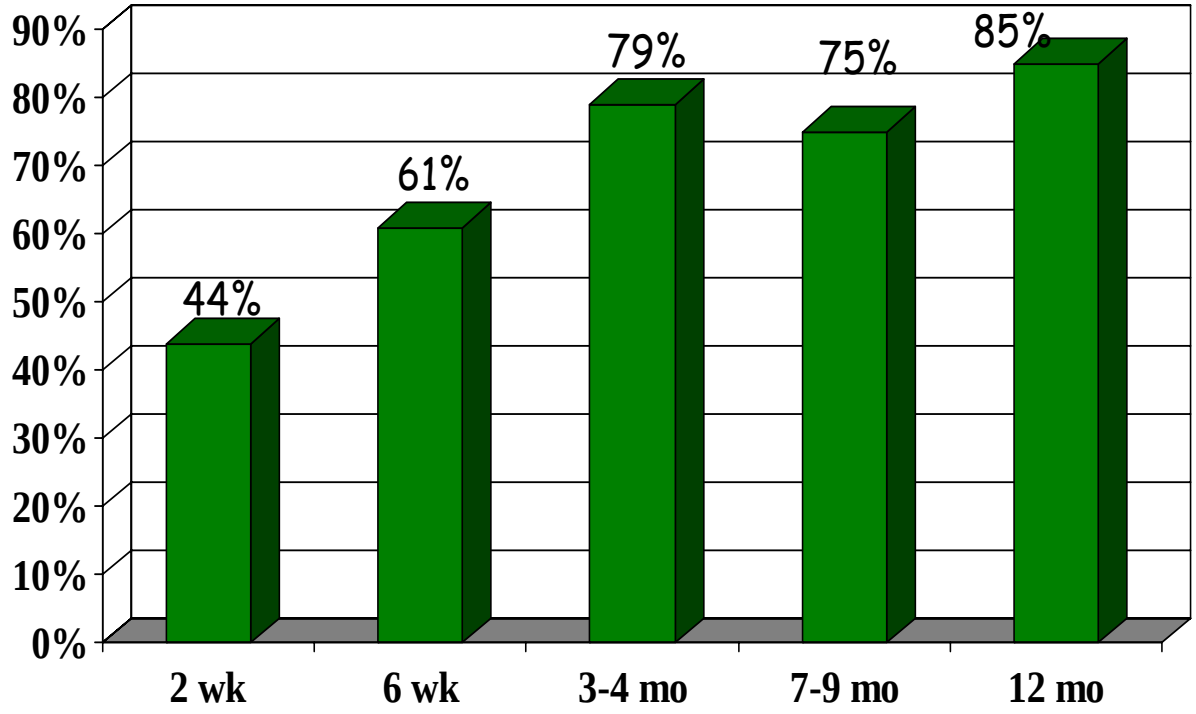
HIV-exposed infants lost to follow up




CORONATION PMTCT CLINIC

Oct 2001 – 2002 (13 months) *Sherman et al. S Afr Med J 2004;94:289*

Oct 2001 – 2003 (24 months) *Jones et al. AIDS Care 2005;17:466*

~40% of HIV-infected infants die by age 1 year

Jones et al. *Bulletin of WHO 2005;83(7):559-560*

**NO DIAGNOSIS**

**NO ACCESS TO HIV CARE !!**

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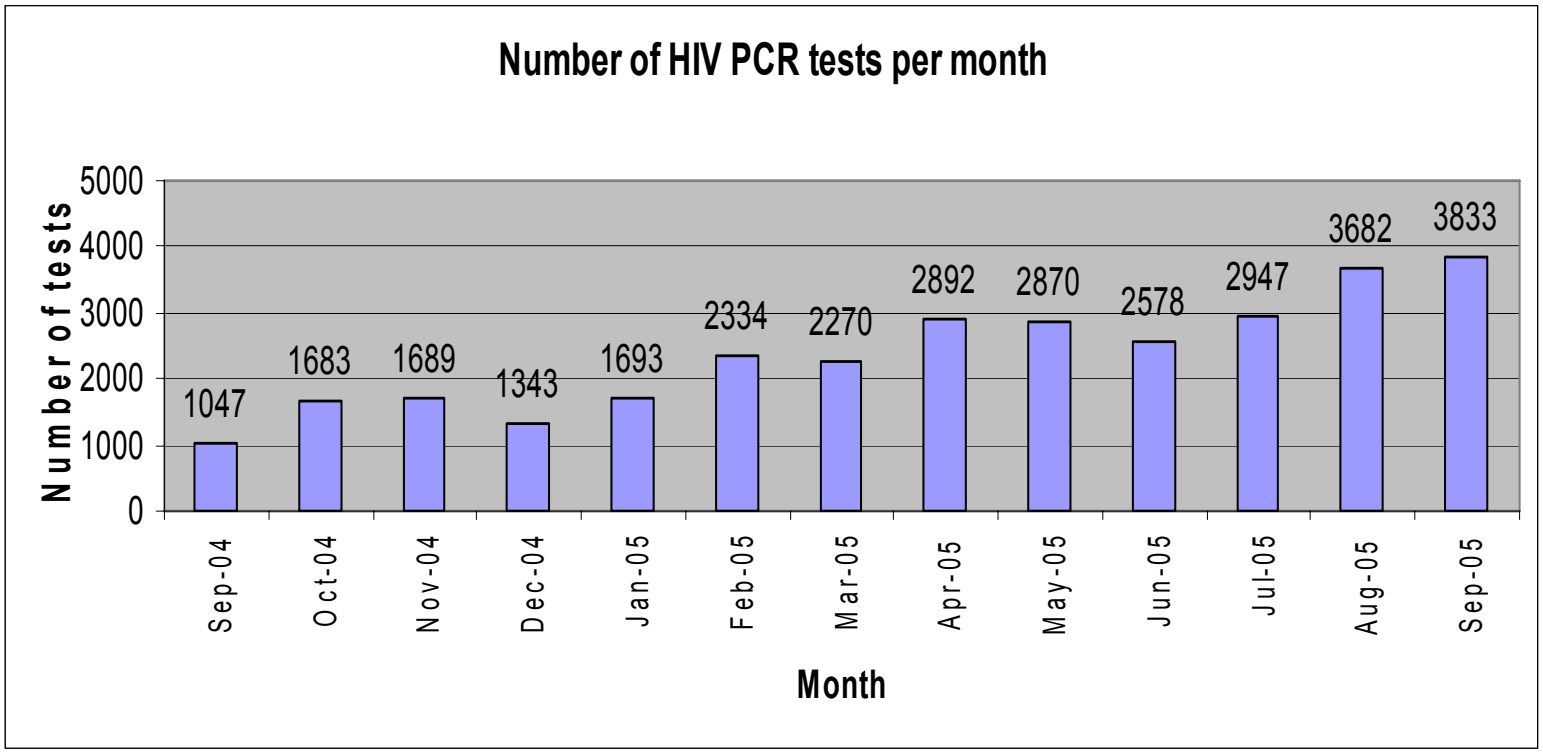


**TARGET** 25 000 tests / month

**CAPACITY** 16%

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# General principles for Management of HIV-infected Children

- Guidelines provide information on management of children with infectious diseases and OI's
- Consistent with IMCI, EDL
- Provides health care workers with basic paediatric knowledge
  - empower health care providers to provide quality care for children
- Guidelines address comprehensive needs of children including, nutrition, counselling, adherence, disclosure, palliative care, legal rights

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# ARV treatment

ARV recommendations based on recommendations from WHO

WHEN TO START

Recurrent (> 2 admissions per year) hospitalisations for HIV complications OR a prolonged hospitalisation for HIV(> 4 weeks) OR

The patient satisfies the modified WHO Stage 3/4 disease OR

For relatively asymptomatic patients, one can consider CD4 percentage <20% if < 18 months or <15% if > 18 months

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# Psychosocial Criteria (children)

- At least one identifiable caregiver who is able to supervise child or administer medication (all efforts should be made to ensure that the social circumstances of vulnerable children e.g. orphans be addressed so that they too can receive treatment)
- Disclosure to another adult living in the same house is encouraged so that there is someone else who can  assist with the child's ART

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# Regimens for Children (SA National Guidelines)

| | 6 months-3years | >3 years (>10kg) |
|---|---|---|
| 1st line | Stavudine (d4T)<br>Lamivudine(3TC)<br>Kaletra® | Stavudine<br>Lamivudine<br>Efavirenz |
| 2nd line | Zidovudine (AZT)<br>Didanosine (DDI)<br>Efavirenz/NVP | Zidovudine<br>Didanosine<br>Kaletra® |

All infants under 6 months of age who require antiretroviral therapy should be started on treatment under specialist supervision.

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# Stavudine

- Original recommended regimen included the use of Abacavir/3TC as NRTI backbone, not approved so D4T recommended together with 3TC
- Liquid stavudine requires refrigeration
  - no refrigerator available, stavudine capsules opened and the contents dissolved in water, the desired amount drawn up and administered to the child
  - Children should be taught and encouraged to take capsules from as early age as possible (4 years)

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# PI selection for <3year olds

- Dose of EFV unknown for children <3 yr and <10kg
- Concern about potency of NNRTI in infants with very high viral loads
- Unclear whether NVP used in suppressive regimen after PMTCT will fail: await further research

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# Follow-up

- Children should be seen 3 monthly, repeat bloods recommended 6 monthly (including CD4, Viral load)
- NB dose amendments with growth
  - Current guidelines provide dosing by weight band to simplify
- Adherence counseling every visit

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# Revised WHO Staging system

- 4-stage system (previously 3-stage) to be similar to adult
  - added to current version of SA guidelines
- Stage 3 and 4 reflect moderate and severe HIV → treatment indicated
- TB stage 3, however CD4 may guide urgency for starting therapy

# Draft WHO Guidelines Criteria of severe immunodeficiency

| | ≤11 months | 12-35 months | 36-59 months | ≥5 years |
|---|---|---|---|---|
| CD4% | ≤25% | ≤20% | ≤15% | ≤15% |
| CD4 count | ≤1500 cells/mm$^3$ | ≤750 cells/mm$^3$ | ≤350 cells/mm$^3$ | ≤200 cells/mm$^3$ |

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# WHO Recommended 1st line ARV Regimens for infants and children

| Regimen of 2 NRTI + 1 NNRTI |
| --- |
| AZT + 3TC+ NVP/EFV |
| d4T + 3TC + NVP/EFV |
| ABC + 3TC + NVP/EFV |

PI not recommended by WHO first line

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# TB and HIV co-infection

- TB extremely difficult to diagnose in children
  - Particularly HIV
- Empiric therapy often necessary when children have a constellation of symptoms and signs
- Recommendations around TB treatment very similar to adults
  - TB Rx  2wks then start ART if very ill
  - Delay ART for 2 months if improving on TB Rx
  - Can push ART out beyond if child doing well on TB treatment
- Continue regimen if on EFV, switch to Ritonavir if <3 years (WHO recommends triple NRTI regimen in this case)

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# Criticisms of guidelines

- No clear guidelines for young infants
- Drug regimens need to be simplified and modified
  - Triple therapy difficult to manage
  - Increasingly reported toxicity in adults and children on stavudine
  - Concern re: 2nd line regimen after PI for 1st line
- Inadequate emphasis on adherence
- Monitoring process not clearly emphasized
- Poor guidance on drug provision/procurement
- Fails to specify when and how children should be counselled
- Doesn't adequately address the needs of OVC in terms of access to treatment
- Inadequate coordination with guidelines for provision of chronic care for children
- **Family** care not sufficiently emphasised

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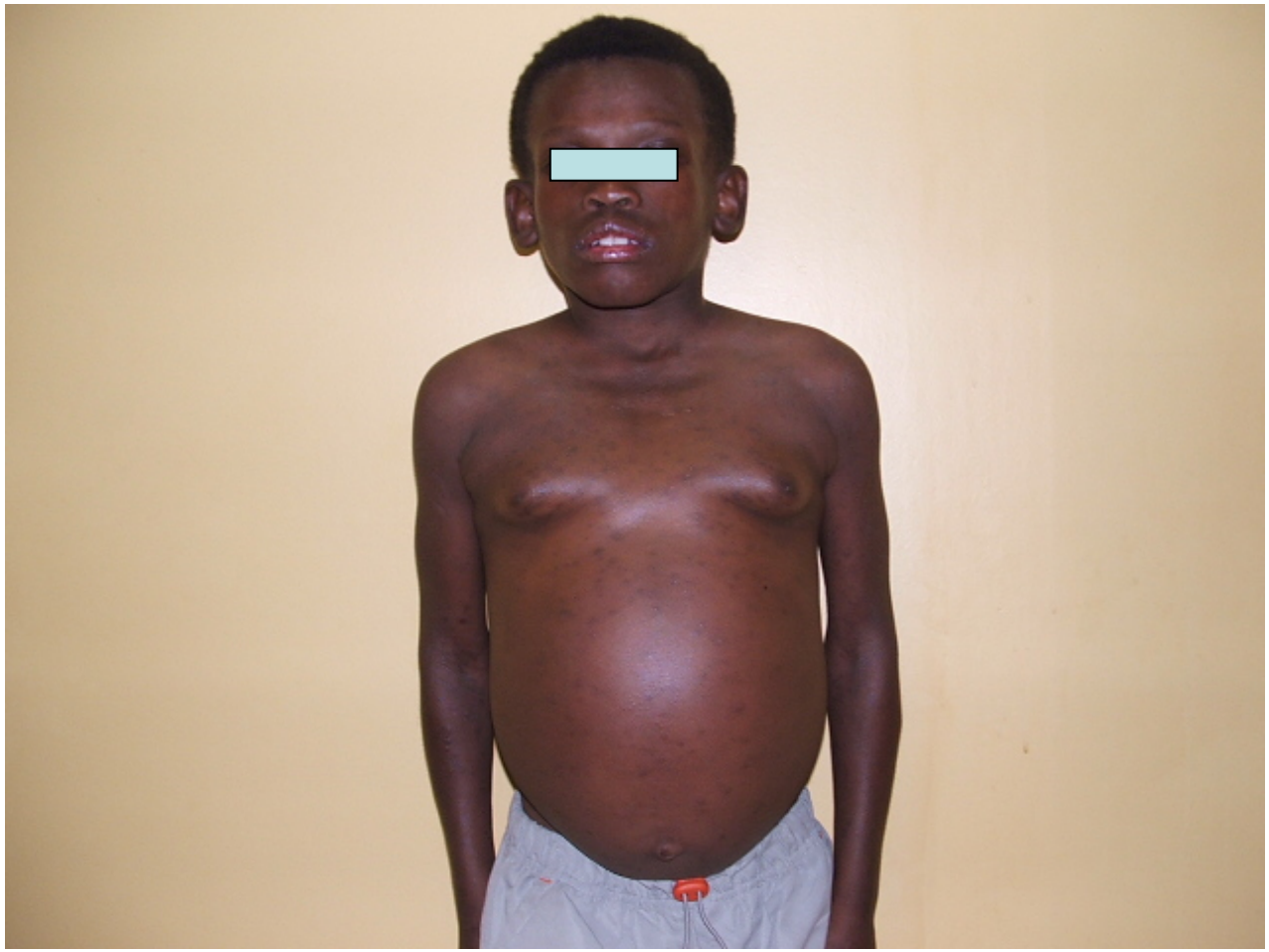

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# Implementation

- Guidelines alone unlikely to change treating practices (provide background information)
  - Dissemination and training
- The guidelines presuppose a certain level of skill which is not there e.g. taking bloods in children
- Drug regimens are very complex
- Guidelines can sometimes become a barrier e.g. if not all factors are in place, treatment will not happen

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# Recommendations

- Avoid excuses to delay therapy, disseminate and implement current guidelines widely
  - follow this guideline until updates become available
  - Regularly check government website for updates: www.doh.gov.za
- Provide training in all provinces and standardise the program
- Form task team to address criticisms and need for updates as a matter of urgency
- National task team to update guidelines on 6-monthly basis on the web
- Investigate mechanisms to disseminate updated information to those with no internet access

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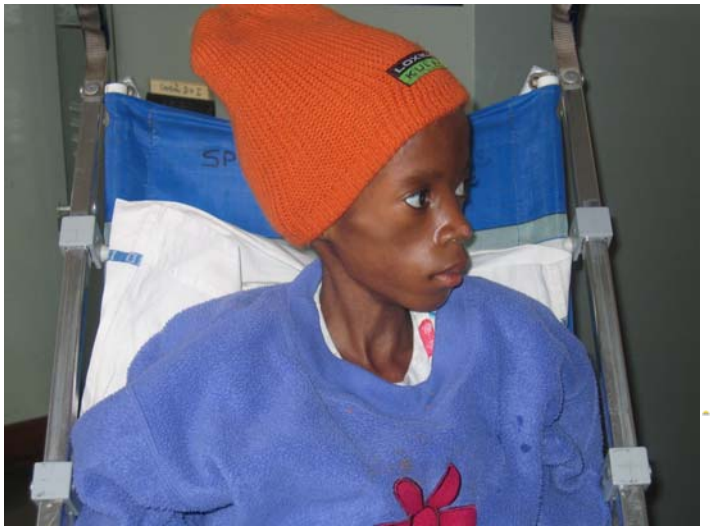
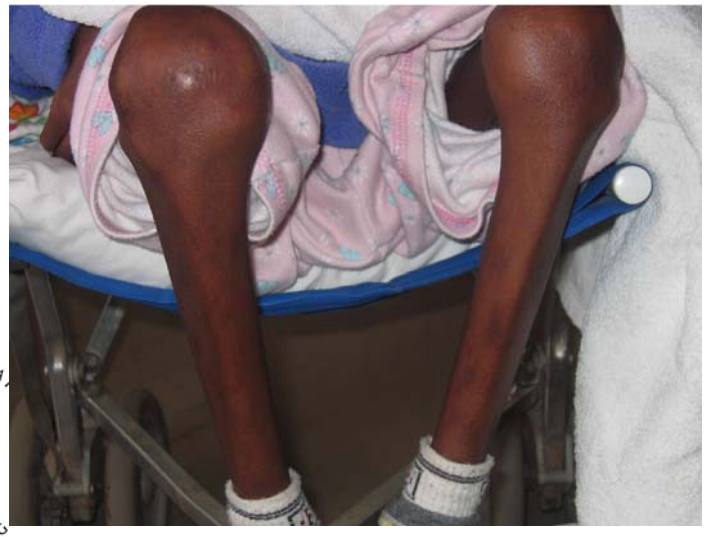
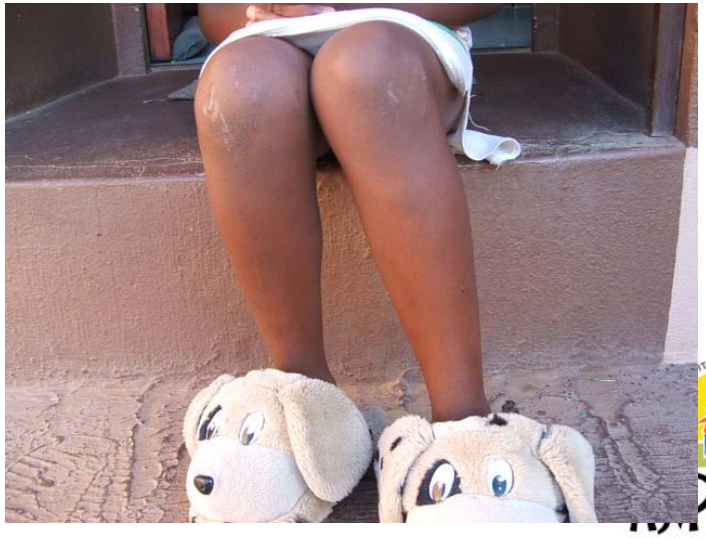
pictures of children before and after ART

**before**





**after**



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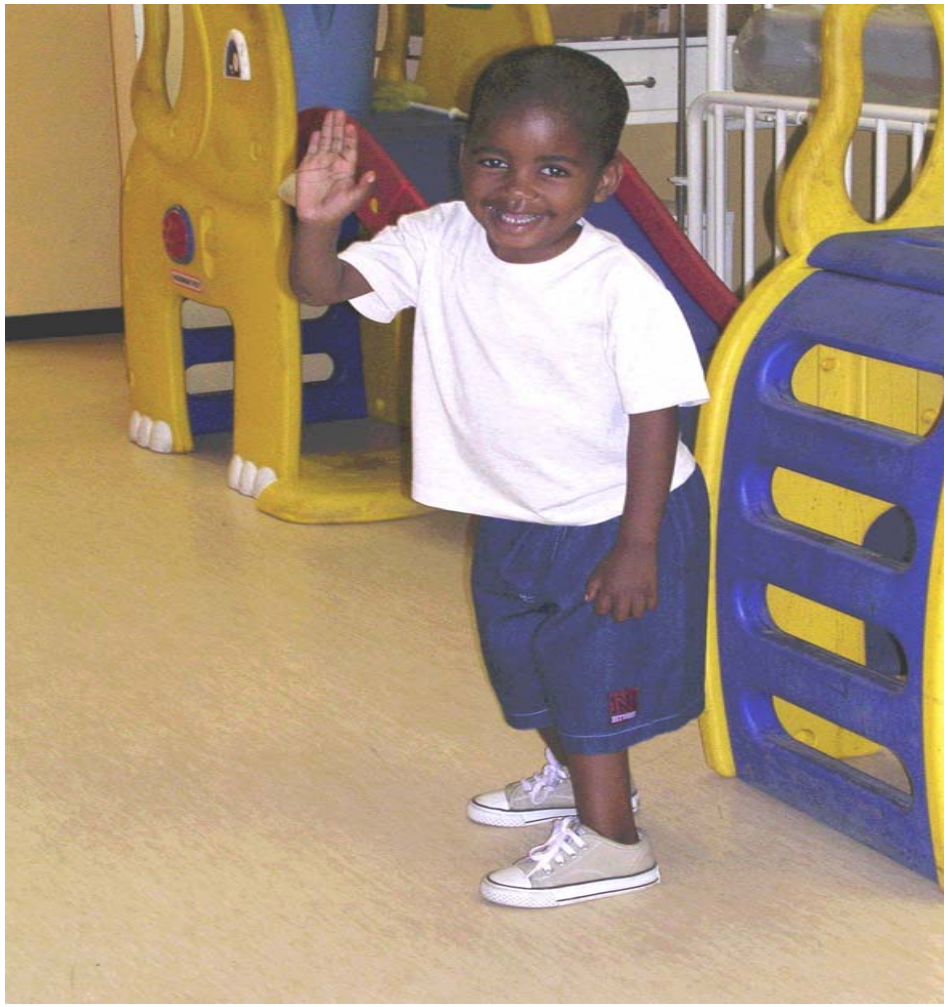
# Thank You



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